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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,145	08/21/2006	Richard Beliveau	0480-0165PUS1	5957

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EXAMINER
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GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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07/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/556,145	<b>Applicant(s)</b> BELIVEAU ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 11-13, 16-31, 33-35, 39-41 and 52-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 14, 15, 32 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. Claims 10 and 38 have been amended.  
Claims 1-9, 11-13, 16-31, 33-35, 39-41, and 52-54 remain withdrawn.
2. Claims 10, 14, 15, 32, and 36-38 are under examination.
3. The following office action contains NEW GROUNDS of Rejection.

#### ***Objections Withdrawn***

4. The objections to the specification and claim 10 are withdrawn in view of applicant's amendments to the specification and the claim.

#### ***Rejections Withdrawn***

5. The rejection of claims 36-38 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's declaration providing evidence supporting treatment of cancer with soluble p97 in non-p97 expressing cells.
6. The rejection of claims 10 and 14 under 35 U.S.C. 102(b) as being anticipated by Gabathuler, et al. is withdrawn upon further consideration by the examiner.

***Rejections Maintained / NEW GROUNDS of Rejection***

***Claim Objections***

7. Claim 14 is objected to because of the following informalities: the claim identifier is incorrect. The claim is listed as withdrawn but the claim is under examination. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. The rejection of claims 32 and 36-38 under 35 U.S.C. 102(b) as being anticipated by Gabathuler, et al. is maintained.

Applicant's response filed April 17, 2008 has been carefully considered but is deemed not to be persuasive. The response states that the Applicants wish to submit that the reference of Gabathuler et al. relates to drug delivery compositions for enhanced delivery of chemotherapeutic agents to tumors in or around the brain, for reducing the systemic toxicity of chemotherapeutic agents used in treating tumors in and around the brain. This reference teaches that chemotherapeutic agents, which are

linked to p97, thus forming a p97-chemotherapeutic agent complex, are excellent vehicles for enhanced delivery of chemotherapeutic agents to brain tumors and other neoplasia located on or around the brain and for improved treatment of such tumors and neoplasia. As clearly stated on page 1, paragraph [0008] in Gabathuler et al., the invention disclosed in the mentioned reference "demonstrates that chemotherapeutic agents which are linked to p97, thus forming a p97-chemotherapeutic agent composition, are excellent vehicles for enhanced delivery of the chemotherapeutic agents to brain tumors". Nowhere is there any teaching or suggestion in Gabathuler et al. that soluble p97 alone can regulate the activation of plasminogen, cell migration or angiogenesis. On the contrary, the reference of Gabathuler et al. as a whole only teaches that the p97 is a transporter of chemotherapeutic agents to the brain (see paragraph [0002] describing the purpose of the invention). Further, this enhanced delivery is only demonstrated for brain tumors and not other types of cancer. There is no teaching or suggestion in Gabathuler et al. of using non-conjugated soluble p97 for treating cancer (see response page 13).

In response to this argument, the instant claims as written are drawn to a composition comprising p97. The Gabathuler composition comprises p97. The conjugated agent may or may not be included in the instant composition as claimed. Regarding the method claims 36-38, the claims recite administering the composition according to claim 32 for treatment of cancer of which brain cancer is included in the list of cancer types in claim 38. Thus, the composition comprising p97 as taught by

Gabathuler which is used to treat brain cancer reads on the instant claims because of the open language recited in claim 32 regarding the composition.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

10. Claims 10, 14, 15, 32 and 36-38 rejected under 35 U.S.C. 102(e) as being anticipated by Jefferies, et al. (US PAT 6,455,494, filed April 1, 1999).

The claims recite a method for treating cancer caused by cells expressing melanotransferrin (p97) at their surface, said method comprising the step of administering to a patient in need thereof exogenous soluble p97 or an antibody or active fragment thereof, directed to said p97 expressed on the surface of said cell, said soluble p97 competing with the p97 expressed on the cell surface, activating plasminogen in solution instead of membrane-bound plasminogen, thus preventing cell migration, said antibody, or active fragment thereof binding p97 on the surface of the cell thus preventing activation of membrane-bound plasminogen, preventing cell migration, preventing cancer cells from spreading, wherein said cell is a tumor cell, wherein said cell is selected from the group consisting of human vascular or microvascular endothelial cells and human melanoma cells. A pharmaceutical composition for use in treating cancer comprising a therapeutically effective amount of one of melanotransferrin (p97), an enzymatically active fragment thereof, or an antibody recognizing specifically p97, or an antigen binding fragment thereof, in association with a pharmaceutically acceptable carrier. The claims also recite a method of treating cancer, comprising administering to an individual a therapeutically effective amount of a

pharmaceutical composition according to claim 32, wherein said administering is carried out orally, parenterally, subcutaneously, intravenously, intramuscularly, intraperitoneally, intraarterially, transdermally or via a mucus membrane, wherein said cancer is selected from the group consisting of melanoma, prostate cancer, leukemia, hormone dependent cancer, breast cancer, colon cancer, lung cancer, skin cancer, ovarian cancer, pancreatic cancer, bone cancer, liver cancer, biliary cancer, urinary organ cancer (for example, bladder, testis), lymphoma, retinoblastoma, sarcoma, epidermal cancer, esophageal cancer, stomach cancer, cancer of the brain, cancer of the kidney, and metastasis thereof.

Jefferies, et al. teach a pharmaceutical composition comprising soluble p97 (column 14 lines 13-17) for treating cancer, particularly skin cancer (column 8 line 7). Jefferies, et al. teach p97 was initially discovered as a cell surface marker associated with human skin cancer (column 29 lines 5-8). Since the claims recite a composition comprising p97 for treating cancer and Jefferies, et al. teach a composition comprising p97 for the treatment of skin cancer, all the limitations of the claims have been met.

### ***Conclusion***

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

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(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

June 27, 2008

/David J Blanchard/  
Primary Examiner, Art Unit 1643